Specialized Program of Research Excellence (SPORE)

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(http://spores.nci.nih.gov)

Recent Developments

- 2001-present
 - Guidelines (2001)
 - Program expansion (new organ sites)
 - P30/P50 Working Group Recommendations
 - Program stabilization (59 SPOREs/14 organ sites)
 - Assessment of the NCI SPORE pipeline
 - Translational Research Working Group
- SPORE Guidelines

SPORE Interim Guidelines

- Updated February 17, 2005
- http://spores.nci.nih.gov/applicants/ind ex_applicants.html

Policy Changes for 2004

- NCI establishes a payline for all SPOREs competing in a given year
- No funds available for new organ sites: all applicants (sites) are competing for the same pool of funds (coming from competing renewal applications)

SPORE Programs

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	1992-93	1995-96	1999	2000	2001	2002	2003	2004	2005
Breast	4	6	6	9	9	9	9	10	8
Prostate	2	3	3	4	8	11	11	11	11
Lung	2	3	3	3	6	6	7	7	7
GI	1	2	2	2	2	4	4	5	4
Ovary	-	-	4	4	4	4	4	5	4
GU	-	-	-	-	1	1	2	2	2
Skin	-	-	-	-	1	2	2	3	3
Brain	-	-	-	-	-	2	2	4	4
H & N	-	-	-	-	-	3	3	4	4
Lymphoma	-	-	-	-	-	2	2	3	3
GYN							2	2	2
Leukemia							1	1	1
Myeloma							1	1	1
Pancreas*							3	3	3
Total Programs	9	14	18	22	31	44	54	61	57
Totals Budget (M)	20	30	39	48	68	112	123	135	133

^{*} Special Initiative in response to Pancreatic Cancer PRG

Receipt Dates for SPORE Applications

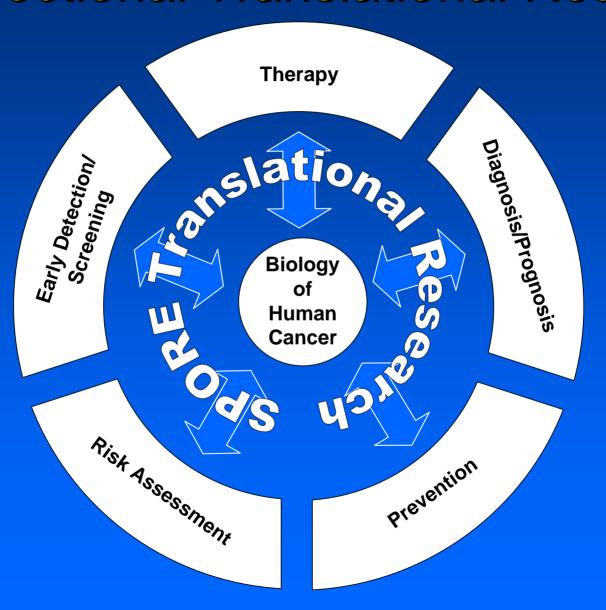
In 2006, all organ sites will be accepted for the September 20rd receipt date.

In 2007, all organ sites will be accepted for the January 23nd, May 22nd, and September 21st receipt dates.

Definition of Translational Research

Translational research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in humans *AND/OR* determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer

Bi-Directional Translational Research



SPORE Eligibility and General Features

- Institution (domestic for profit and not for profit)
- Basic and Clinical Research Base
- Access to Patients
- Budget Cap (reduced to \$2.5M)
- Team Concept

- Inter-SPORE and NCI/NIH Network Collaborations (greater emphasis)
- Flexibility to Realign Resources
- Scientific Outreach
- Data/Resource Sharing (NEW)
- Standing Special Review Panel (NEW)

SPOREs Budget Caps

- \$2.5 mil. Total Cost for Year 1
- \$1.5 mil. Direct Cost for Year 1
 - may be exceeded by indirect costs of subcontract(s)
- Up to 3% Cost of Living Increase for Year2 and Subsequent Years
- Applications that Exceed these Caps (including cost of living allowance) will be Returned without Review

SPORE Requirements

- Statement of Institutional Commitment
- Intellectual Property
 Management Plan (NEW)
- 4 Translational Research Projects (including "required")
- Shared Cores
 (specimen core required; adm, stats, & clinical are common)

- Developmental Research Program
- Career Development Program
- Commitment to attend and participate in SPORE Workshop and related NCI/NIH Meetings (NEW)
- Other Provisions for NCI designated Comprehensive Cancer Centers

SPORE: Institutional Commitment

- Letters of Support from the Institution
- Incorporation of the SPORE within its Institutional Priorities
- Allocation of Discretionary Resources to the SPORE Program (e.g., funds for DRP, CDP)
- Facilitation and Promotion of Scientific Progress
- Integration of SPORE activities with NCIdesignated Cancer Center

Integration of SPORE with NCIdesignated Comprehensive Cancer Center (CCC)

- Principal Investigator: Prominent within CCC
- Lines of Authority
- Organizational Relationships
- Separate Institutional Commitment
- Augmentation of Existing CCC Resources: Cores
- Program Coordination with CCC Activities

SPORE Principal Investigator Qualifications:

- Basic/Clinical Investigator Recognized Scientific Leader in the Field
 - Provides Leadership/Direction to the SPORE
 - Oversees and Conducts Planning Activities
 - Project Leader/Co-investigator/Core Director
- Appropriate Time Commitment (>25%)
- Understands Translational Research Objectives
- Identifies New Translational Research Opportunities

Research Projects

- Test Novel Translational Ideas
- Balance between Basic and Applied Research
- Human Application within 5 yr of the Award
- Project Co-Leaders (2-3)
- Interdisciplinary Interactions
- Human Subjects/Animal Protections
- Consortium/Contractual Arrangements
- Data/Resource Sharing Plan
- Consultants/Commercial Agreements

SPORE Cores

- Tissue Collection and Distribution (Required)
 - Parameters of collection and preservation; pertinent analytical considerations; essential pathological, clinical, family history information and linkage to databases, etc. (more detail)
- Other Specialized Cores
 - Administrative
 - Clinical
 - Biostatistical
 - Bioinformatics
 - Others
- Building on Pre-Existing Resources; Avoidance of Duplication
- Cross-talk between Cores and Projects
- Data Management within Program Description (NEW)

Career Development Program

- Encourages New and Established Investigators to Develop Careers in Translational Cancer Research
- Provides Salary and Other Support
- Promotes Mentoring of New Investigators
- Recruitment Plan for Selection of Candidates, including Women & Minorities
- Plan for Solicitation, Review, and Award
- → (Promotion to Full Project on SPORE)

Developmental Research Program

- Pilot Projects that Explore Innovative Ideas
 - Basic Research Projects with *Translational Potential*
 - Early Phase Clinical Studies; Pilot Epidemiology Projects
- Takes Advantage of New Research Opportunities
- Promotes Collaborations Among Scientists at the Same or Different Institutions
- Supports Research Proposed by Independent Investigators
- Plan for Solicitation, Review, and Award
- Promotion to Full Project on SPORE

Annual SPORE Investigator's Workshop

- Statement of Commitment (within Program Description)
- Budget to Fund 10 Investigators to the Workshop (Admin Core)
- Promote Inter-SPORE Collaborations
- Share New Ideas, Materials, and Technologies
- Identify New Research Opportunities
- Establish Research Priorities that will Impact Upon Cancer Detection, Prevention, or Treatment
- Resolve Research Needs by Making Recommendations to the NCI Leadership
- Interact with Patient Advocates, NCI Staff, and industrial representatives